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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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10/21/97 07/14/00 VALLEF

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EXAMINER

DELABROIX-MURHEI, C

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

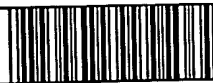
# Office Action Summary

Application No.  
09/616,718

Applicant(s)  
VALLEE et al.

Examiner  
Cybille Delacroix-Muirheid

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 14, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

The following is responsive to the Preliminary amendment received July 14, 2000.

Claims 7-12 are cancelled without prejudice or disclaimer.

Claims 1-6 are presented for prosecution on the merits.

### ***Claim Rejections - 35 USC § 112***

1. Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites a method for therapeutically treating alcohol consumption in a human. However, this limitation is vague and indefinite because it is not clear to one of ordinary skill in the art whether this method is used for treating humans that are addicted or dependent on alcohol. The specification, however, clearly states that the method is used to reduce alcohol consumption for purposes of treating alcohol abuse. Therefore, it is respectfully requested that Applicant amend the claim to read --A method for therapeutically reducing alcohol consumption in a human in need thereof, comprising administering to the human a compound of Formula I...--. The claims therefore will be consistent with the specification and will more clearly portray that which Applicant believes to be the invention.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keung et al.

Keung et al. disclose methods of inhibiting ALDH-2 in human livers as well as methods of reducing the intake of ethanol by hamsters. Specifically, both methods comprise administering effective amounts of daidzin or analogs thereof to human liver cells and to the hamsters. The results show that daidzin as well as most of the analogs successfully inhibited ALDH-2 in human liver cells and also reduced ethanol intake by the hamsters by inhibiting ALDH-2. Please see the abstract; page 1676, Materials and Methods; page 1677, col. 1, last full paragraph to col. 2, Discussion; page 1678, second col., last full paragraph; Table 4.

Keung et al. do not disclose inhibiting ALDH-2 in a human (in vivo) nor do Keung et al. disclose reducing ethanol consumption in a human; however, it would have been obvious to one of ordinary skill in the art to administer daidzin and its analogs to a human because in view of the desirable results obtained by Keung et al. using human liver cells and in view of the successful reduction of ethanol intake by hamsters as a result of ALDH-2 inhibition, one of ordinary skill in the art would reasonably expect daidzin and its analogs to effectively inhibit ALDH-2 and thus reduce alcohol consumption in humans.

With respect to claims 4 and 5, because the prior art discloses substantially similar methods and compounds, the specific aldehydes and neurotransmitters affected would be obvious.

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### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,886,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '028 claim a method for therapeutically treating alcohol consumption in humans by administering compounds represented by Formula I in the instant application and represented by the "formula" in USPN '028. The claims of the instant application differ from the claims of USPN '028 in that USPN '028 administers a narrower subgenus of compounds. That is to say that the method claims of USPN '028 do not require that substituent "R" comprise a peptide moiety, sugar moiety or polyether.

However, the scope of the claims of the instant application overlap with the claims of USPN '028 because the remaining groups identified for substituent "R" are identical and further because claim 3 of the instant application is broader and encompasses the subgeneric compounds of USPN '028.

7. Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,624,910. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '910 claim a method for therapeutically treating alcohol consumption in a human by administering daidzin to the human. The claims of the instant application differ from the claims of USPN '910 in that the method claims of USPN '910 specifically administer daidzin and not its analogs.

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However, the scope of the claims of the instant application overlap with the claims of USPN '910 because claim 3 of the instant application is broader and encompasses the more specific species, i.e. daidzin, of USPN '910.

8. Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,624,910 or claims 1-10 of U.S. Patent No. 5,886,028 in view of Keung et al.

USPN '028 and '910 as applied above.

USPN '028 and '910 do not claim a method for inhibiting ALDH-2 in a human; however, the Examiner refers to Keung et al., which discloses that suppression of ethanol intake in hamsters is linked to the inhibition of ALDH-2. Therefore, inhibition of ALDH-2 as claimed in claims 1-2 would have been obvious in the method claims of USPN '028 and '910.

### ***Conclusion***

Claims 1-6 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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CDM

July 25, 2001

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600